

## SF424 (Grants.gov) Application Changes

**FORMS-F** application packages are to be used for due dates **on or after May 25, 2020**.

**FORMS-E** application packages are for due dates **on or before May 24, 2020**.

Links to notices and updated instructions:

- [Notice Number: NOT-OD-20-026](#)
- [FORMS-F checklist](#)
- [SF424 Application Guide Instructions Version F](#) - Updated Application Guides for Form F:
- [Annotated Forms F](#)
- [High Level Form Change Summary Forms F](#)

## Key Changes

### Cover Letter

- Instructions updated to indicate that it must not be used to communicate assignment preferences
- If using Human Fetal Tissue obtained from elective abortions (HFT), include a statement

### PHS Assignment Request Form

- Language updated to clarify that this form is for suggestions.
- Removed the “Do Not Assign to Awarding Component” and “Do Not Assign to Study Section” fields and instructions.
- Added new “Rationale for assignment suggestions” field.

### R&R Budget

Applications including HFT:

- R&R Budget must be used for applications including HFT. Modular budgets cannot be used, regardless of activity code
- Must include “Human Fetal Costs” line item in budget section (F. Other Direct Costs, lines 8-10) whether or not you incur costs to obtain HFT. If no costs are incurred, enter 0 under funds requested. This line item cannot be combined with any other costs.
- The Budget Justification is to include the quantity, type(s), and source(s) of the HFT, including the stage of fetal development. The HFT Justification must be clearly labeled.

Additional updates:

- Section F. Other direct costs –note removed regarding requesting an exception to sIRB policy
- Lines “8-10 Other” may be used to request direct costs related to the use of single Institutional Review Board (sIRB) for multi-site human subjects research.

## PHS 398 Research Plan Form

- For applications proposing HBT, must include specific information in the Approach section of the Research Strategy attachment. Detailed instructions can be found in the SF424 Application Guide.

## PHS Cover Page Supplement form

- New Human Fetal Tissue Section
- New field: "Does the proposed project involve human fetal tissue obtained from elective abortions?" field.
  - For multi-projects, if human fetal tissue will be used in any component, you must answer Yes in the Overall Component.
  - Attachment for HFT Compliance Assurance – **Required if YES**
  - Attachment for HFT Sample IRB Consent Form– Required if YES

## PHS Human Subjects and Clinical Trials Information

### Use of Human Specimens and/or Data

- Reworked landing page to require an answer and supporting explanation (if applicable) for the question "Does any of the proposed research in the application involve human specimens and/or data?" for all applications.

## Study Record: PHS Human Subjects and Clinical Trials Information

### *Clinical Trial Questionnaire*

- Does the study involve human participants? – defaults to YES when the answer to "Are Human Subjects Involved" question on the R&R Other Project Information form is YES.
- Added NEW "Inclusion of Individuals Across the Lifespan" attachment. Updated instructions for the "Inclusion of Women and Minorities" attachment to reflect separate "Inclusion of Individuals Across the Lifespan" attachment.
- **NIH: Single IRB plan no longer required**. A statement naming the sIRB of record will be provided at Just-In Time. AHRQ: Single IRB plan required.
- Is this an applicable clinical trial under FDAAA?" – New field and checkbox
- "Provide the ClinicalTrials.gov Identifier": -Optional. Enter NCT # for the study if available. Newly proposed studies do not need to be in ClinicalTrials.gov at time of application.
- "Section 2 – Study Population Characteristics" instructions now reflect updated exceptions for required questions.
- "Data and Safety Monitoring Plan" attachment – required for CT study; optional for HS study
- Added new "Inclusion Enrollment Report Title" field.
- Removed the "Brief Summary" field.
- Changed the "Narrative Study" field to "Detailed Description."

## R&R Senior/Key Person Profile

- Career Development and Fellowship applications
  - eRA Commons profile associated with the credential agency username must include an ORCID ID.

## PHS Fellowship Supplemental Form

- New attachment "Description of Candidate's Contribution to Program Goals" to the Institutional Environment and Commitment to Training Section
- This attachment is only for applicants to diversity-related FOAs. All other fellowship applications should skip this section.
- Not required as part of the Admin Shell; however, needs to be attached prior to finalization.